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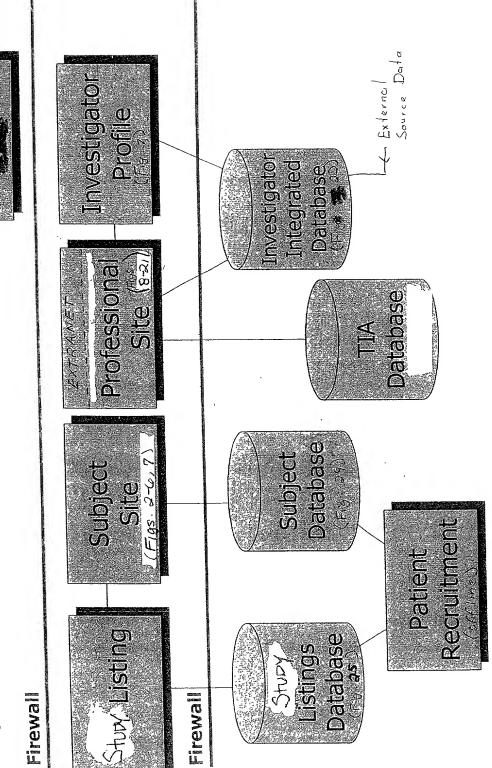


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# Clinical Trials FAQ

- Introduction: What are clinical trials?
- > Why are clinical trials important?
- The clinical trial process.
- How are participant's rights and safety profested during a clinical trial?
- Who pays for clinical trials?
- Where can you get more information about clinical trials?
- Questions you need to ask.
- Common terms used in clinical trials.

### Introduction: What are clinical trials?

Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the

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drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

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# Why are clinical trials important?

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

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### The clinical trial process.

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

Phase I. In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these trials.

Phase II. In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

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Phase III. In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended. Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

Phase IV. Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

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# How are participant's rights and safety protected during a clinical trial?

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

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# Who pays for clinical trials?

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.
- Sponsors may pay you to participate in a clinical trial.
   Typically, these fees, when provided, are nominal.
- Medical care is often provided at no cost to the



patients, but they still may be responsible for other expenses such as travel between their homes and the healthcare facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

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# Where can you get more information about clinical trials?

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your healthcare provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

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# Questions you need to ask.

- What is the length of your involvement in the clinical trial? How long will the trial last?
- Where will you have to go in order to participate in the clinical trial?
- What are the possible treatments you may receive while in the clinical trial?
- Do the treatment alternatives they provide cover all possible treatments for this disease? If not, what are your other treatment alternatives?
- What procedures are built into the study to keep you safe from harm while you are participating?
- What are the risks and benefits of participating in the clinical trial?
- If there are risks, what will happen should you have an adverse reaction to the treatment in the study?
- What costs may you incur if you participate?
- Will the treatment be available to you even after the clinical trial has concluded?
- Where are the funds coming from to conduct this trial? What is their purpose in sponsoring the trial?

You should also feel free to ask any other question about the trial you want answered.

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### Common terms used in clinical trials.

Clinical trial: A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and



benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

Clinical investigator: A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

Coordinator: A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

Food and Drug Administration: The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

**Informed consent:** Informed consent is a process that confirms a patient understands the nature of the study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

Institutional Review Board: An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

Investigational treatment: Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

Principal investigator: The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

**Protocol**: A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

**Sponsor:** The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.



Standard treatment: Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the 'best treatment' currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

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When a promising new medication is identified, careful evaluation of the safety and effectiveness of the drug then occurs in the clinical trials process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. Findings from the clinical trials are

medical specialties. Findings from the clinical trials are reported by the pharmaceutical or biotechnology company that is sponsoring the clinical trial to the US Food and Drug Administration — the FDA. Only after the FDA has determined from reviewing the findings from clinical trials that the medicine is both safe to use and effective is it then made available for broader use by doctors and their

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Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on

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clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

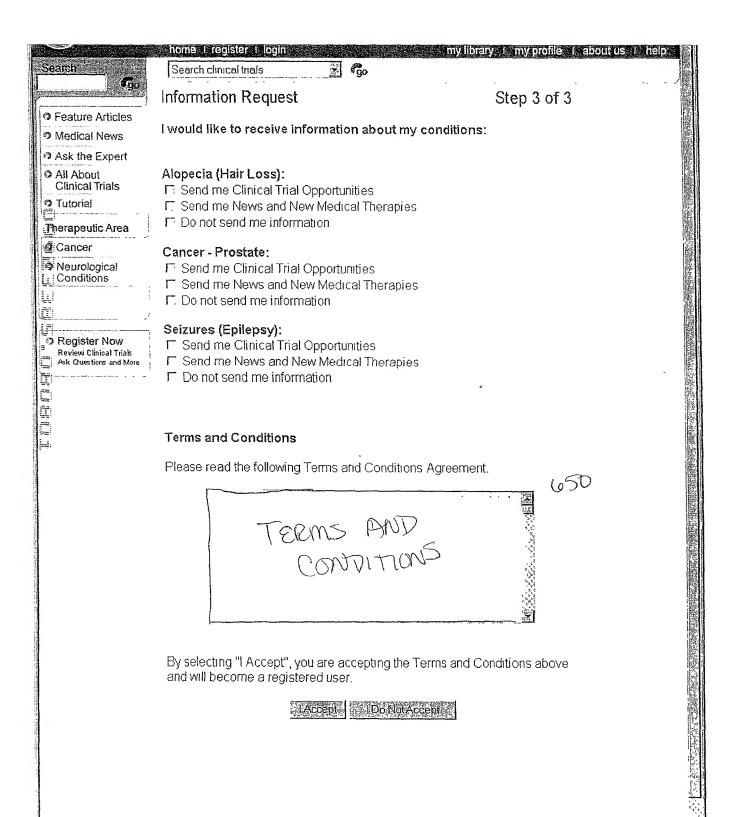
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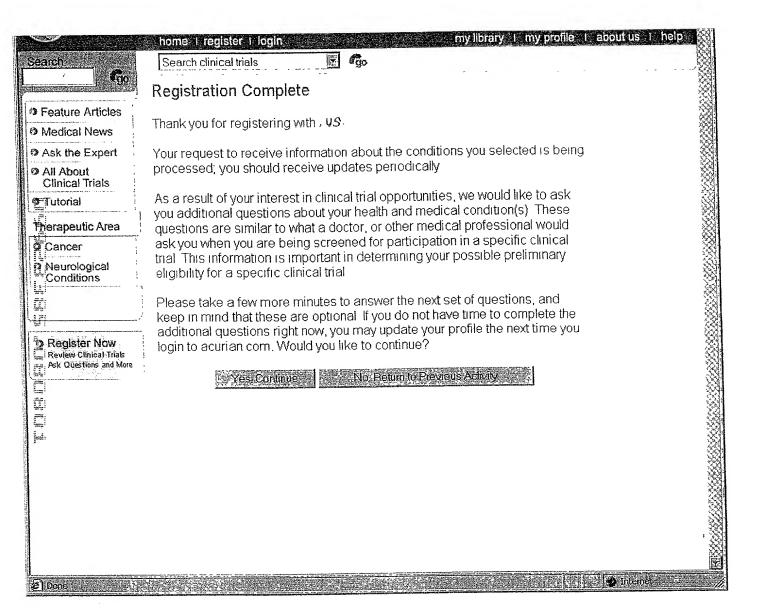
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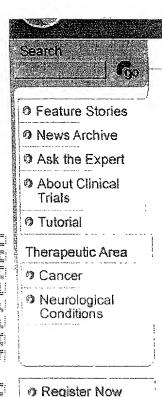
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| (go)   | Health Habits (Optional) St   | ep 2 of 5  |
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| 2 :: : :<br>2 :: : : : : : : : : : : : : :   | How often do you visit your primary care physician?   |  |
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| Andreas  | Do you smoke cigarettes?  |  |
|  | ○ No, I have never smoked   | 上<br>200   |
| Andreas  | C No, I guit smoking  |  |
| the state of the s | C Yes, daily C Yes, occasionally  |  |
|  | res, occasionally   |  |
|  | If you smoke, how many cigarettes do you smoke per day?   |  |
|  | Please enter Cigarettes Per Day   |  |
|  | , ,   | 11.00  |
|  | If you smoke, how old were you when you started smoking?  |  |
|  | Please enter   years old  |  |
|  | Do you drink alcoholic beverages?   | 1200   |
|  | C No  | J. G.  |
|  | ○ Yes, occasionally   | S. C.  |
|  | C Yes, 1-2 drinks per day   | 7.00 XXX   |
|  | ☐ Yes, more than 2 drinks per day   |  |
|  | Overall, how would you rate your health?  |  |
|  | © Excellent   |  |
|  | ○ Good  | ).<br>**<br>**   |
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| <ul><li>Peature Articles</li><li>Medical News</li><li>Ask the Expert</li><li>All About</li></ul> | drug against a specifi   | efully structured study that evalua<br>c disease or condition Clinical<br>sed to determine new uses for e | trials can focus on a new            |      |
| Clinical Trials  Tutorial Therapeutic Area   |  | ns ask about your experience ar<br>uestions are to help us know ho<br>Inical trials before.               |                                      |      |
| Cancer Neurological Conditions   | How many clinical tria  0  1  2  3  4 or more  | lls have you participated in?   |                                      |      |
| Register Now Review Clinical Trials Ask Questions and More                                       |  | l you be in participating in a clini<br>nedical condition(s) you may ha<br>sted                           |                                      |      |
|  | If interested in clinical participate in a clinical participate in a clinical Conference of 1 - 10 miles Conference of 51 - 100 miles Conference of Any distance |   | d you be willing to travel to        |      |
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|  | Clinical Trial Questions   | Step 4 of 5  |  |
| Feature Articles   | Earlier in the registration process, you expressed in  | ntoract in clinical trial  |  |
| Medical News   | opportunities. When you are screened for a clinical  | trial, the doctor at the trial site  |  |
| Ask the Expert  All About  | needs to know more information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may           |  |  |
| Clinical Trials  | help determine if you may potentially qualify for a sp   |  |  |
| • Tutorial   | Listed below are the conditions you selected earlie  | r in the questionnaire. After you  |  |
| Therapeutic Area   | answer questions about each condition, a check m   | ark will appear to the right   |  |
| A Cancer   | Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time |  |  |
| Neurological<br>Conditions   | you login to acurian com   | Sale your promotion nove time  |  |
| Facility :   | Qı   | uestionnaire   |  |
| 7.2  | -  | Complete   |  |
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| O All About Clinical Trials  | top of the page. We ask   | that you review your pro                            | file at least once a month, so that  |
| Tutorial 9   | we may have the most a<br>trial or medical informati                  |   | n trying to present you with clinical  |
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| Cancer   |   |   | de us with any comments you this registration process.   |
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Review Clinical Trials Ask Questions and More Search clinical trials v go

# Home / Knowledge Center /

# 612

# Welcome to My Library

Here's your chance to create a library of your very own. My Library is where you can store all kinds of information found throughout the site. Whether it's clinical trial information, abstracts on news articles, drug information, perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as long as you choose to keep them there. All you have to do is click the "Save to My Library" button found throughout the site.

In addition, you can type in personal notes along with the items you save. We will not access, use, or review your personal notes for any reason.

If you'd like to go directly to one of the five sections, select a link below:

- News
- Drug Information
- O Clinical Trials
- Ask The Expert
- Feature Stories
- Do not show this page again.



/ / \_ / Investigator Questionnaire **Investigator Questionnaire** Step 1 of 3 Thank you for your interest in joining our investigator database. The following questionnaire will take approximately one hour to complete. The privacy and security of your information is important to us. All information you submit is transmitted over a secure server. Register For more information, read our \_. () h Services 4 Asterisks (\*) denote required fields. O FAQ W. Last Name \* First Name \* Middle Name Degree(s) \* Primary Research Facility's Organization or Institutional Name \* Street Address \* City \* -- Select State/Province --State / Province / Region Country \* -- Select Country --Zip Code / Postal Code \* Phone (with area code) \* Telephone Extension Fax (with area code) **Email Address** Primary Specialty \* -- Select One --O Yes O No Board Certification(s) \* Year of Certification Board Eligible \* O Yes O No Sub Specialty O Yes O No Board Certification(s) Year of Certification Board Eligible O Yes O No Number of years Investigator has participated in trials? \*

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| 30/49   |  |
|---|--|
| Indicate all phases of clinical research in which the Investigator participated *   | 706  |
| How many investigators investigators conduct research at this PRF? *  | 1-70/  |
| Is the Investigator   |  |
| If affiliated with a local IRB, what is its name?   | TOTAL STATE OF THE |
| How often does the local  |  |
| If "other", frequency of local IRB meeting?   |  |
| How soon after the IRB meeting will you receive an approval letter?   |  |
| Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency?  1. If yes, what was the |  |
| date of the audit?  | THE RESIDENCE OF THE SECOND OF |
| Who was the auditor?  If audited, was a 483   | 709  |
| What were the results of the audit?   | armonous d   |
| 2. If yes, what was the date of the audit?  | CONTRACTOR OF THE CONTRACTOR O |
| Who was the auditor?  |  |
| If audited, was a 483 Yes O No issued?  |  |
| What were the results of the audit?   |  |

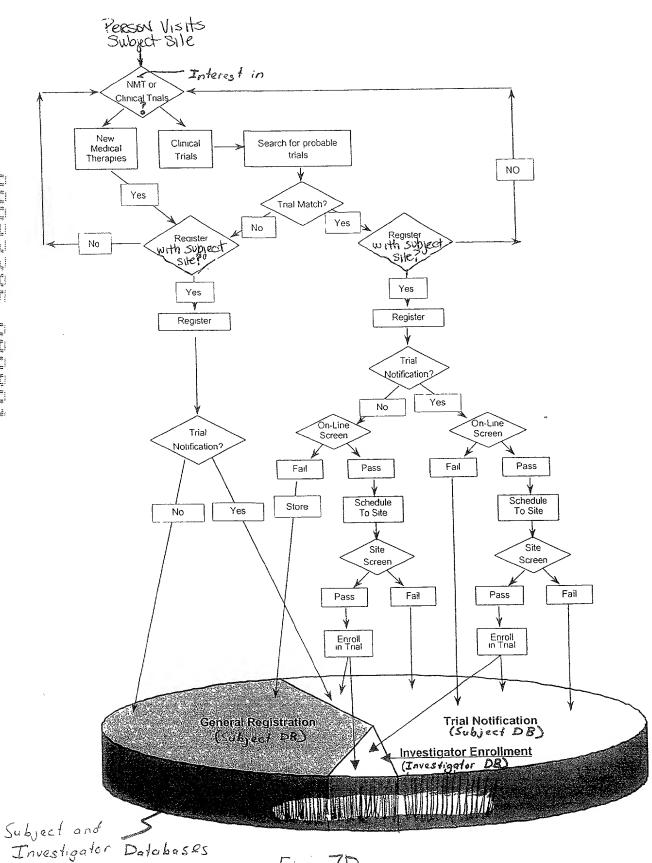
FIG. 7B

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|---|--|---|--------|
| Has the Investigator<br>gone through an audit<br>by a sponsor or CRO? | O Yes O No   |   |        |
| 1. If yes, what was the date of the audit?                            | personal acts fill the strategic one case where the fill of the strategic or the strategic of the strategic or the strategic    |   |        |
| Who was the auditor?  |  |   | - ) 1C |
| What were the results of the audit?                                   |  |   | MC     |
| 2. If yes, what was the date of the audit?                            |  |   |        |
| Who was the auditor?  | VIENCES O STREET TE ESTE MET ENCONECTE LECTURE MEDIONE DI PRESENTATION DE PROPRIO CONTENDIMENTO DE<br>SE LECTURE DE L'ANTINO DE  |   |        |
| What were the results of the audit?                                   | procure authorization for the contract and the contract a   |   |        |
| _   | -  |   |        |
| Is your PRF   | ☐ Single specialty ☐ Multi-specialty   |   |        |
| If PRF is multi-specialty, indicate specialties. (one per line)       |  |   |        |
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| Is your facility part of  | ☐ Solo practice ☐ Group practice   |   |        |
| Is the facility affiliated with a Site Management                     |  |   |        |
| Organization (SMO) or research group?                                 | O Yes O No   |   |        |
| If affiliated, please specify the SMO name                            |  |   |        |
| If affiliated, is this an exclusive relationship?                     | O Yes O No   |   |        |

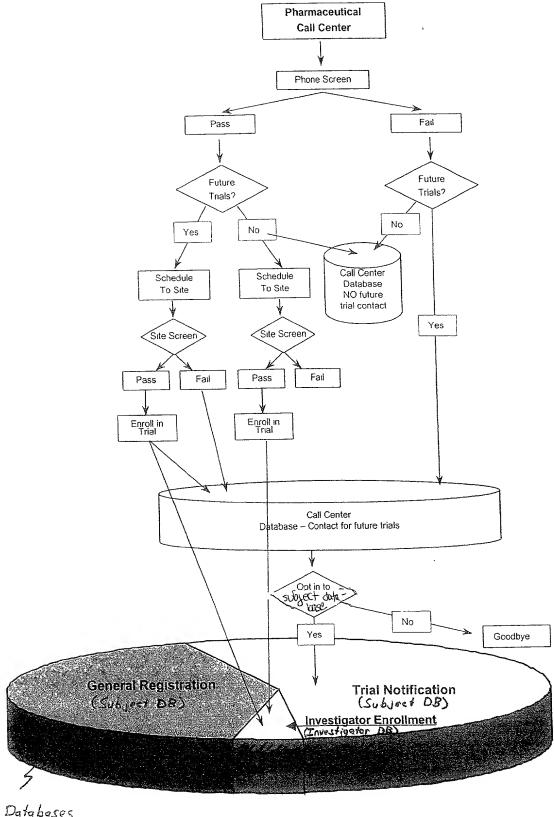
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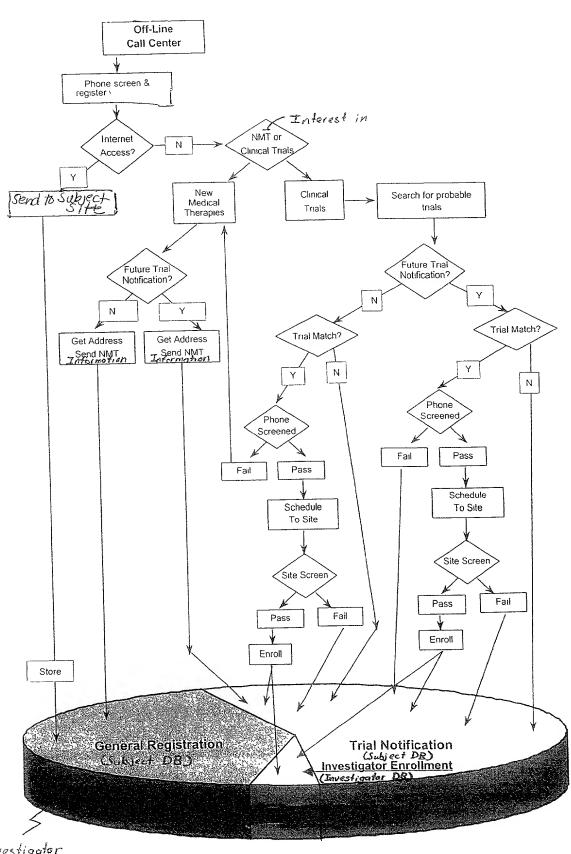


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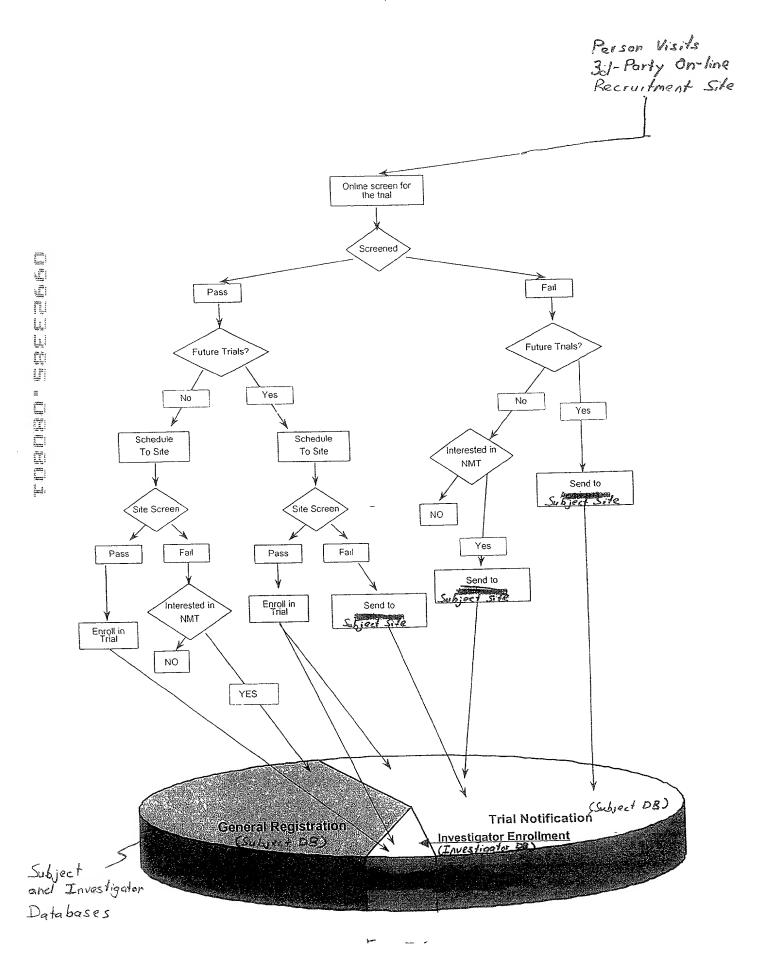
Subject and Investigator Databases

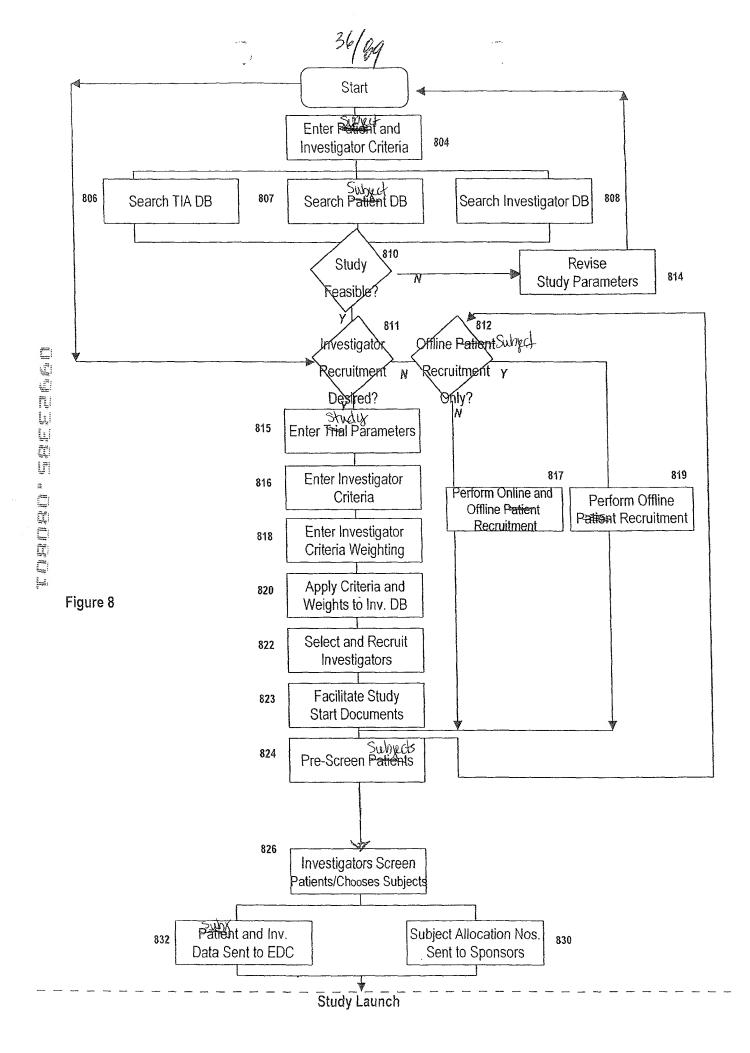
Fig. 7E



Subject and Investigator
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| ling of the second   | Therapeutic Area                                 | Select a Therapeutic Area ▼  |
|  | Disease<br>Indication                            | Select an Indication ▼   |
|  | Projected<br>Number of Sites                     | ACCOUNTS AND THE PROPERTY OF T |
|  | Projected<br>Number of<br>Patients per Site      |  |
|  | Projected Trial<br>Start Date                    | January ▼ 2000 ▼ (Month/Year)  |
| Committee of the commit | Projected Trial<br>Stop Date                     | January ▼ 2000 ▼ (Month/Year)  |
|  | Projected<br>Enrollment<br>Period (in<br>months) |  |
|  | Trial Phase                                      | Select Trial Phase   |
|  |  | ) Save & Search for Investigators  |

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Fig. 9

Step 1:

To identify potential investigators - please select a specialty.

Note: To select more than one specially, paint to the specially and press control click. Limit of 2 selections

Aseliairan Psychietry
Adolescent Medicine
Aerospace Medicine
Allergy & Immunology

Step 2:

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication.

Nate: To select make then one drug class, point to the specialty and plass control class timet of 3 selections. No Drug Glass—
Acne Therapy
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All Other Misc Ethical Drugs

Step 3:

To include the number of trials conducted by the investigator in the search a number. options!

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Step 4:

To access additional databases to enhance the investigator selection proc selections below. \*\*change\*\*

Patient Therapeutic Area

Patient Disease Indication

Patient Disease Indication Encounter Category

Note: To person more than one palient deceate micraien encounter calegory paint to the apeciality and pressionation older fund of 2 selections.

-Select a Category-

Case Load Estimates - Malignancy of heptobiliary system of pancreas Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas

Patient Distance from Site (in miles)

Step 5:

To limit search by geographical location- please enter your selections belo

Municipal Area

–Select a Municipal Area – 🗻

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Displaying 1-20 out of 682 results

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# investigator Search Results

The following investigator search results rolled the investigator search criteria and the patient demographic data selected in the investigator Search, Review selections by scrolling down this page or by clicking here: <u>loyestigator, Search, Criteria, Summary</u>. Click a column heading to sort by that column

| Search Results:    Control   Control |  |
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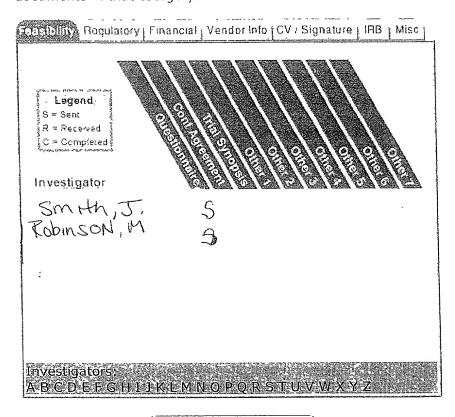
- Document View
- Investigator View

contactus i help

Home / \_\_\_\_\_ / Active Trials / Trial at a Glance / Document Tracking

# A multi-center study... Document Summary

Summary of document status for the selected protocol. Click on any document to go to Document View by Investigator. Click on any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.



> Return to Trial at a Glance

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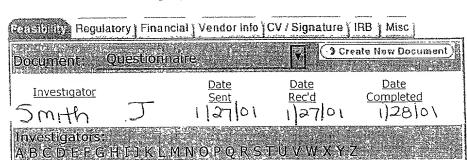
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Active Trials / Trial at a Glance / Document

Tracking / Document View by Investigator

## **Document View by Investigator**

Summary of document status by investigator. Click on any investigator to go to document history of the document selected in the drop down box. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.



Protocol Number 345678

Welcome

- ") Register
- Services
- FAQ
- Document Summary
- Ocument View

RESERVE OFFI

Investigator View

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From: Service Prouder

Sent: June 6, 2000

To: Ms. Moore

Subject: Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to https://www.uebsite.com/study/zz-234567-22\* and complete the study specific questionaire.

Contact Service. Com with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to http://www.servel.com/remove

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant?

Yes, I am the potential study participant

Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.

- o Male
- o Female

How did you hear about this study?

- o Internet
- Newspaper Ad
- o Newspaper Article
- o Radio Ad
- o Radio Public Service Announcement
- o TV Ad
- o TV program
- o Physician
- Friend
- Support Group
- o Patient Ed Materials
- Cardiology Newsletter
- Other, please specify: \_

The purpose of this medical research study is to evaluate the effect of an investigational drug on the ability to reason, remember, imagine, and learn in humans who have already been diagnosed with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive daily visits from a responsible caregiver. The caregiver must be familiar with the your recent medical history and be willing to come to 7 doctor visits for a period of 6 months.

After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other person at the research facility will be calling you. At that time, it will be determined if a first visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease?

- o Yes
- o No

Have you experienced a deterioration in memory over at least the last 6 months?

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- o Yes
- o No

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- o orientation
- o judgement
- o problem solving
- o functioning in community affairs
- o functioning in home or hobbies
- o functioning in personal care

Do you live in a residential home?

- o Yes
- o No

Click the box next to the person who will serve in the role of Caregiver:

I am the Caregiver

Friend

Relative

Paid personnel

No Caregiver

1. Please enter your date of birth:

Day

Month

Year (pull-down boxes)

- ☐ If female, continue with question 2
- ☐ If male, continue with question 6
- 2. Are you / Is (Patient) surgically sterile or post-menopausal for 1 year or more?
  - o Yes continue with question #6

No – continue with question #3

- 3. Do you / Does (Patient) have any other neurological conditions such as:
  - o Parkinson's disease
  - o Pick's disease
  - Huntingtons chorea
  - o Down's syndrome
  - o Creutzfeldt-Jacob disease
  - o Other
- 4. Do you now or did you at any time, have one or more of the following conditions resulting in your memory or *cognitive* impairment:

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F

- Major head injury
- Injury caused by trauma such as boxing
- Vitamin deficiency
  - O Type [drop down menu]
- o Brain abscess
- o Syphilis
- o Meningitis
- o AIDS
- o Brain cancer
- O Thyroid, parathyroid, or pituitary disease
- o Cushing's syndrome
- o Kidney failure
- o Uncontrolled diabetes
- Mental retardation
- 5. Do you have a history of any of the following:
  - O Stroke within the past 12 months
  - o Epilepsy or convulsions (Childhood convulsions caused by fever continue)
  - o Major depression
  - Stomach ulcer that is currently being treated
  - o Liver, kidney, or lung disease
  - o Kidney stones
- 6. Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months?
  - o No
  - o Yes
- 7. Do you experience angina (chest pain) that required a change in medication in the past 3 months?
  - o Yes
  - o No
- 8. Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute?
  - o Yes
  - o No
- 9. Do you take medication for high blood pressure or chronic low blood pressure?
  - o Yes
    - o Medication(s) taken: [drop down menu]
  - o No
  - o Don't know

F16. 15C



- 10. Do you take any medications for the purpose of treating memory loss such as dementia?
  - o Yes
  - o No
- 11. Are you allergic to any medications?
  - o Yes
    - O Which Medication(s) [drop down menu]
  - o No
- 12. Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba?
  - o Yes
    - O Which Medication(s) [drop down menu]
  - o No
- 13. Have you ever been enrolled in a research study for galantamine?
  - o Yes
  - o No
  - o Don't know
- 14. Have you taken an investigational drug in the past 30 days or are you taking one now?
  - O No, I have not taken an investigational drug in the past 30 days
  - O Yes, I have taken an investigational drug in the past 30 days
  - Yes, am taking an investigational drug now
- 15. How many drinks do you consume in a typical 24-hour period?
  - o 1-2 drinks
  - o 3-5 drinks
  - o 6-8 drinks
  - o more than 8 drinks
- 16. Have you/patient had a CT scan or MRI of the head during the last 12 months?

Yes

No

# SCREEN #2: PATIENT NOT ELIGIBLE FOR STUDY

We appreciate your interest in this study. Unfortunately, from the information you have provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies?

- o Yes, contact me.
- o No, I do not want to be contacted.

F16, 15E

### SCREEN #3: PATIENT POTENTIALLY ELIGIBLE FOR STUDY:

Based on your responses, you may be eligible for the clinical study. We will forward this information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5-7 business days, please feel free to call the number that will be included in your mailed materials.

In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies?

- o Yes, contact me
- o No, I do not want to be contacted

F16.15F

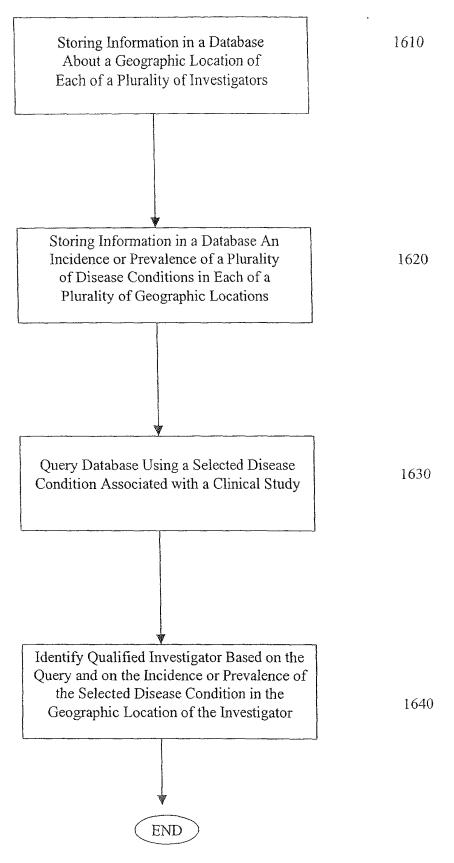
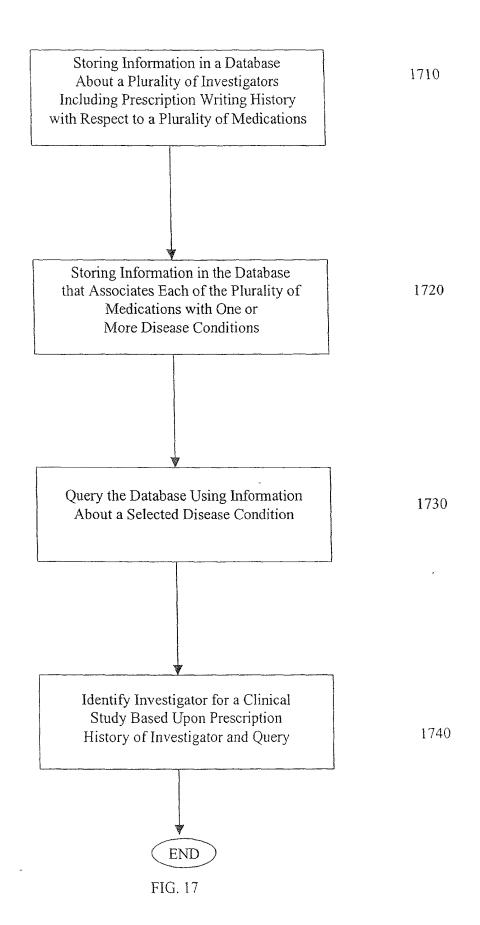
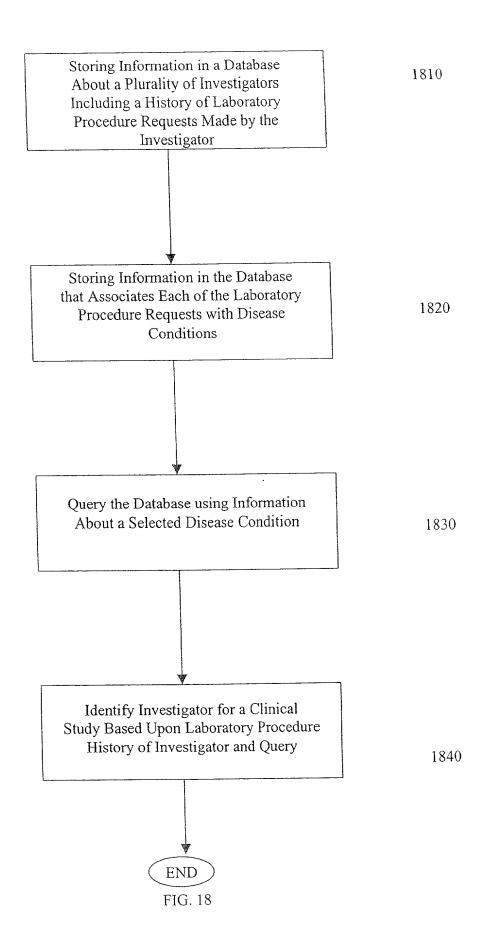


FIG. 16







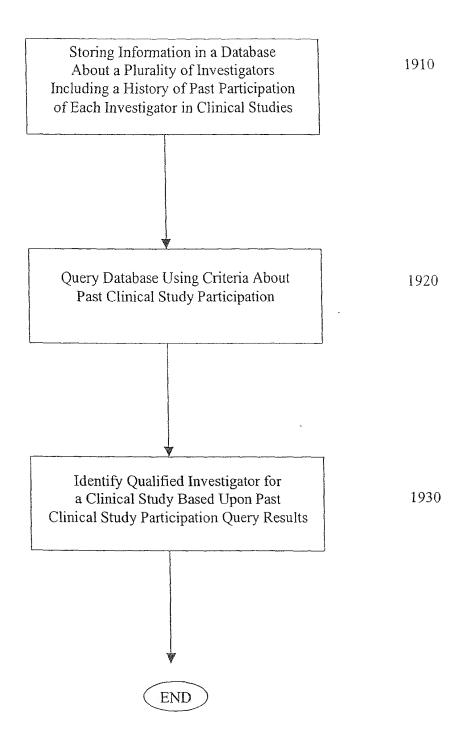
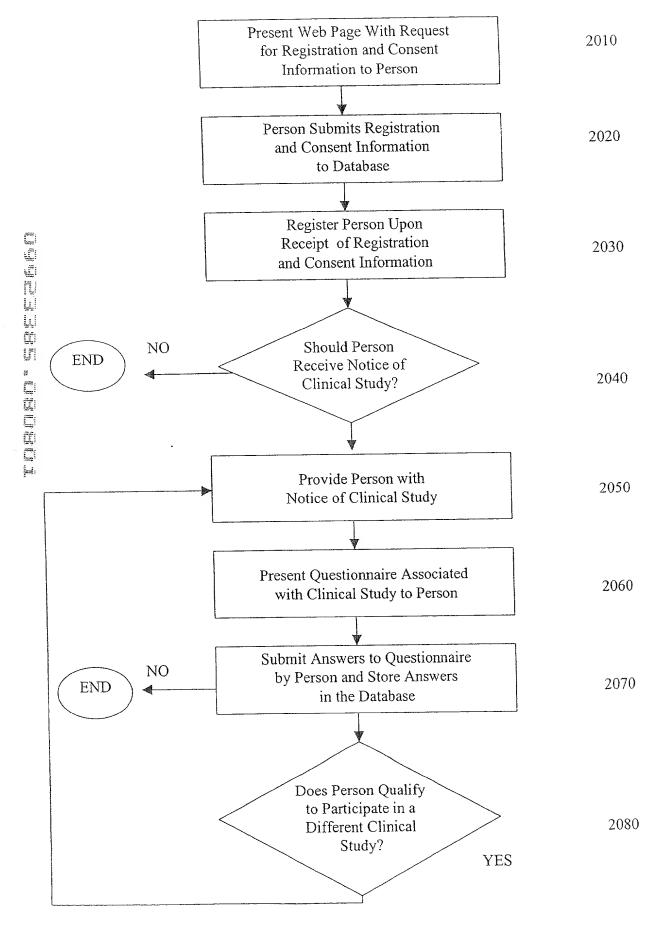
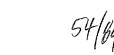


FIG. 20





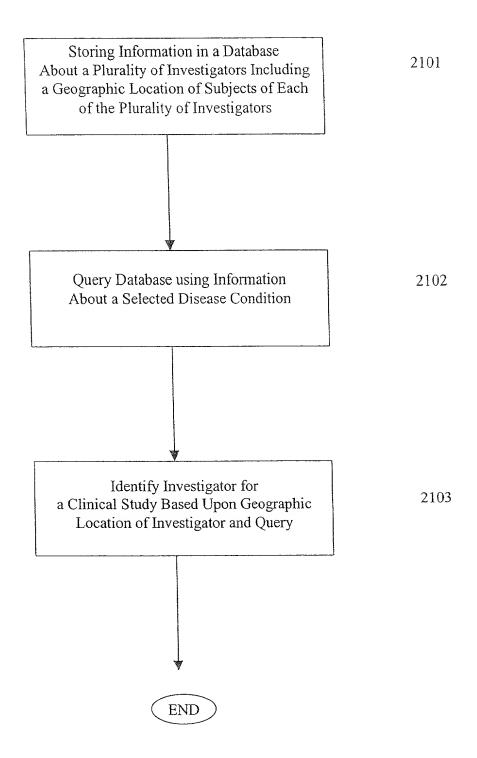
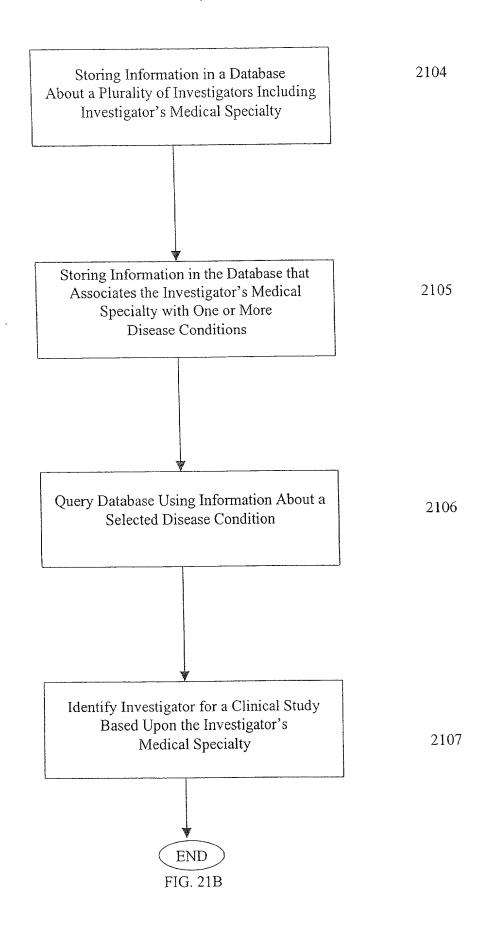
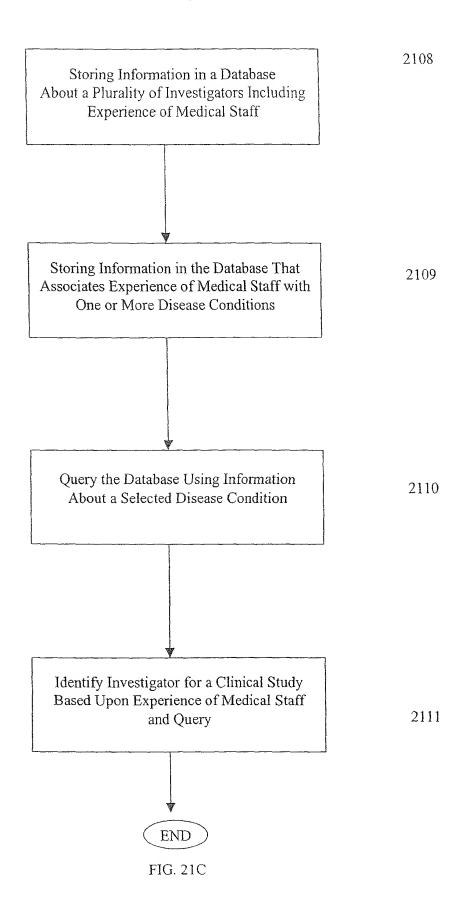


FIG. 21A





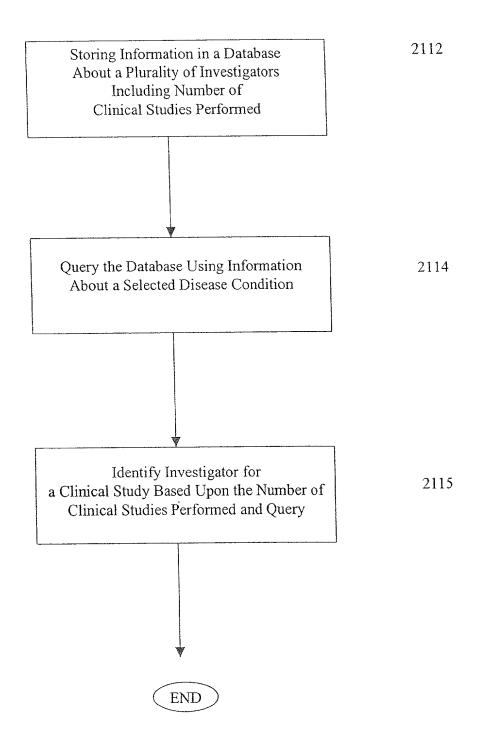
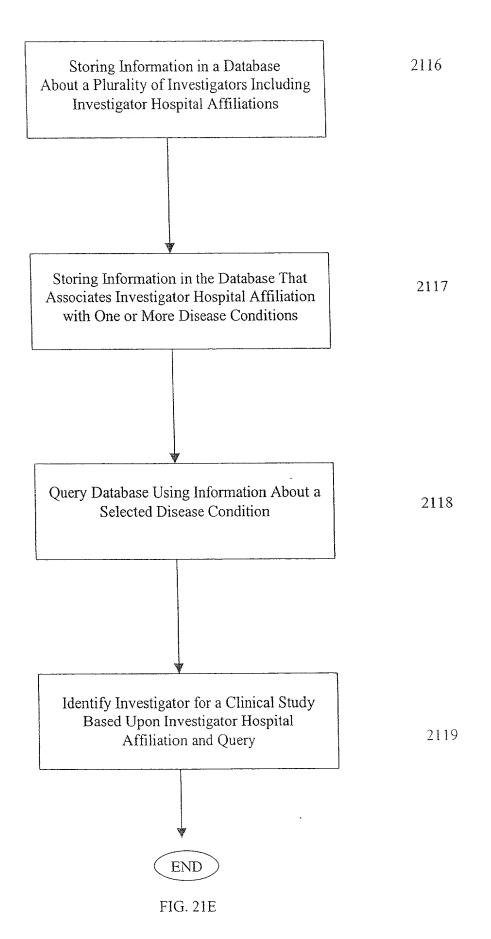
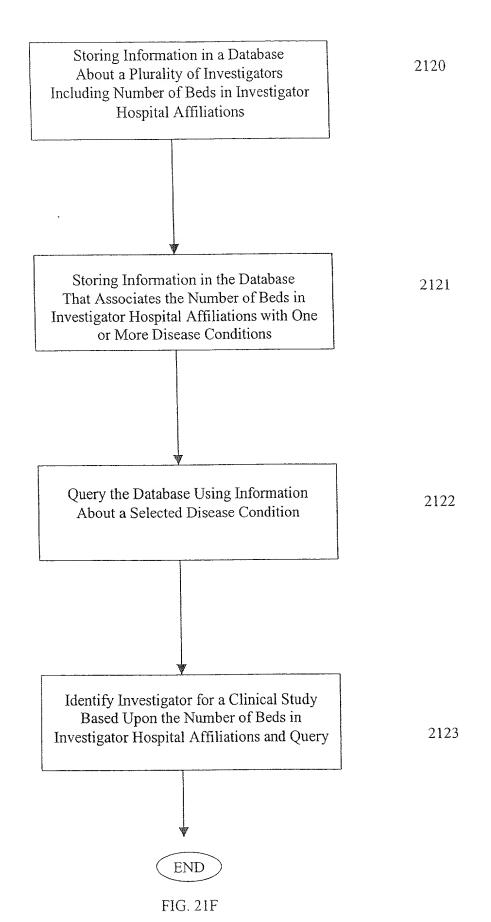


FIG. 21D







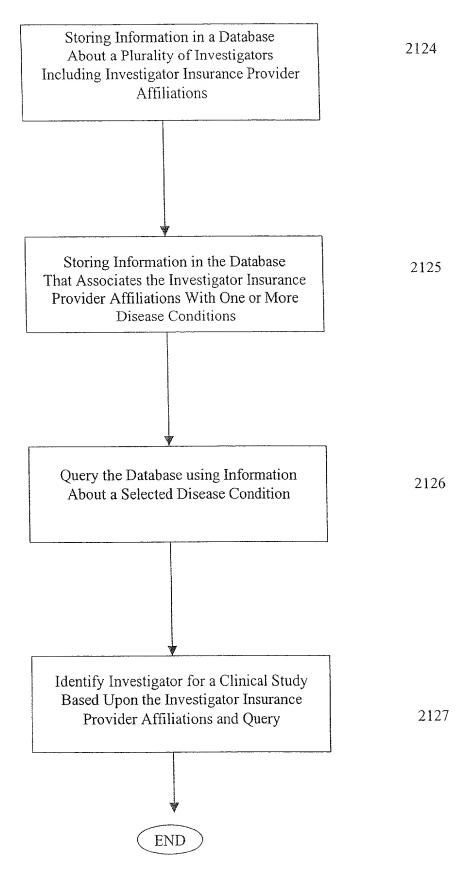


FIG. 21G



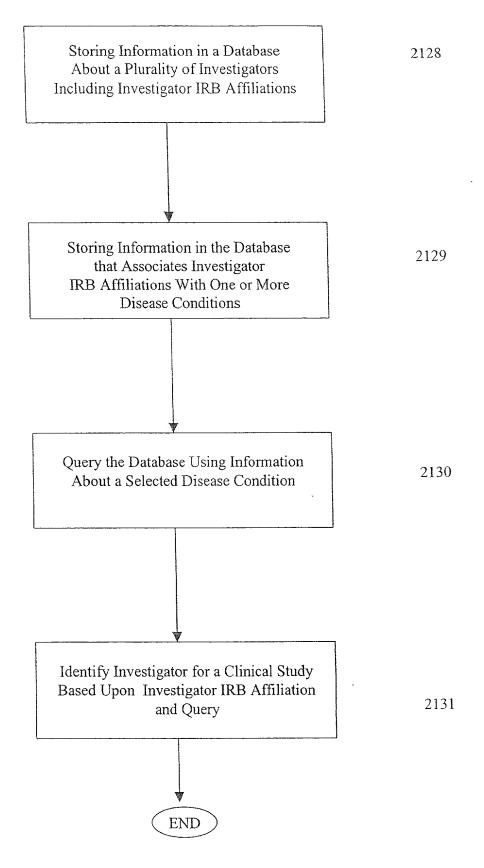


FIG. 21H

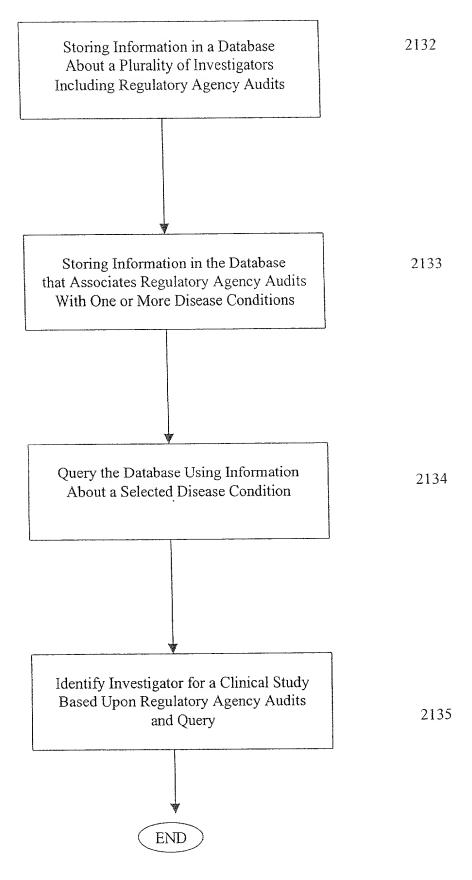
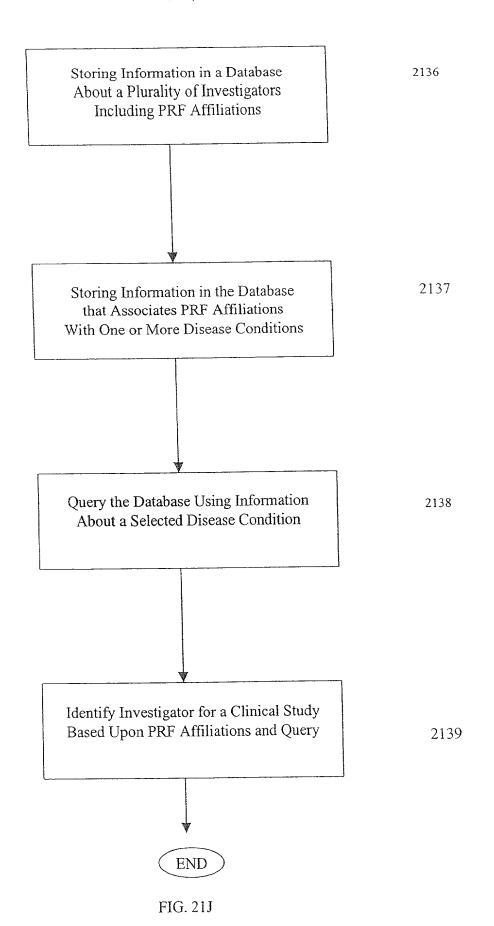


FIG. 21I





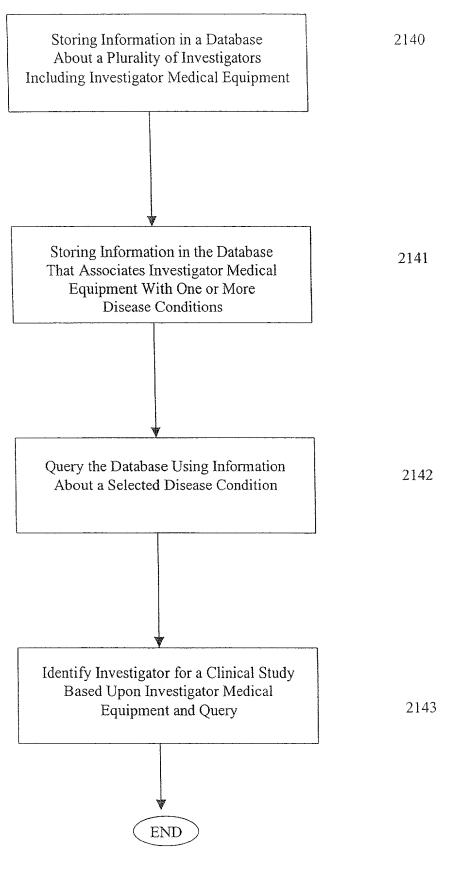
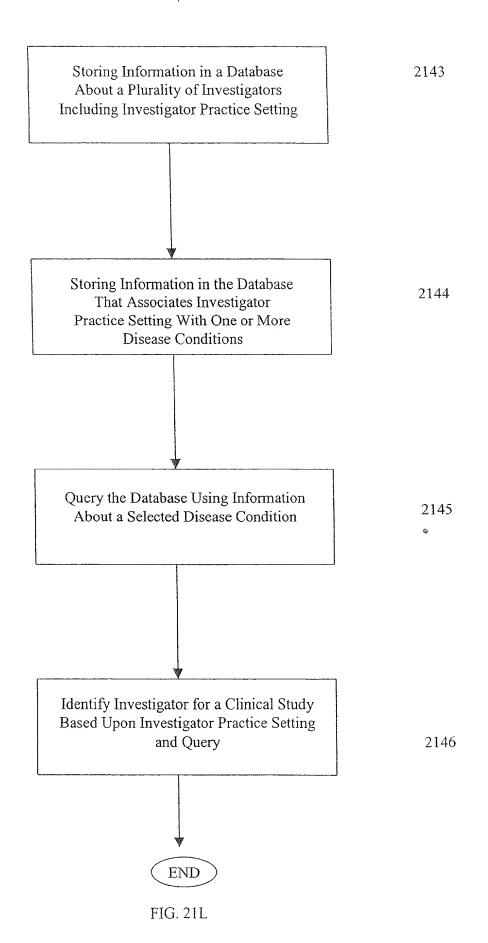
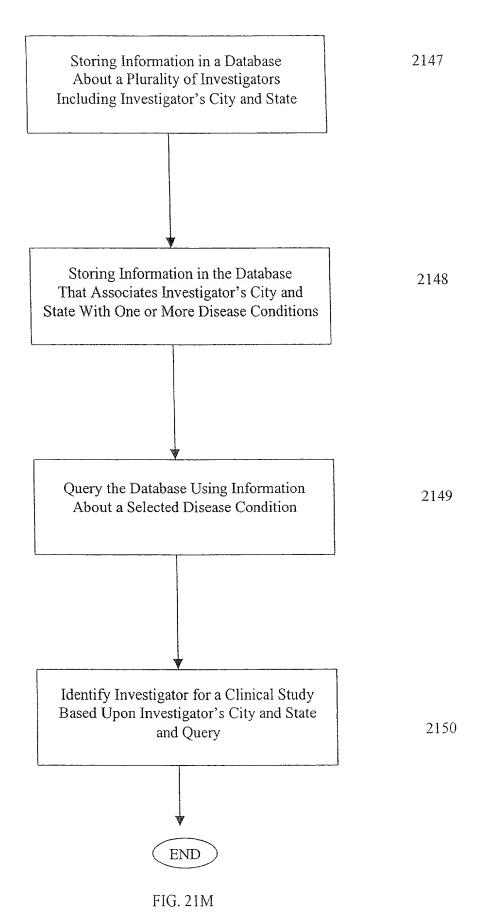
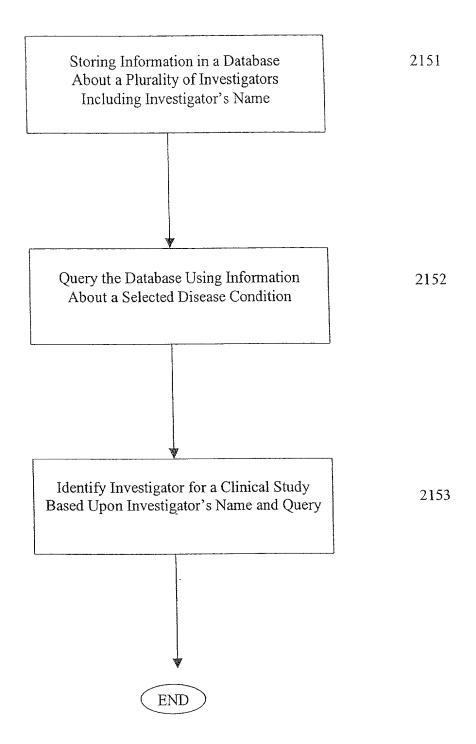


FIG. 21K









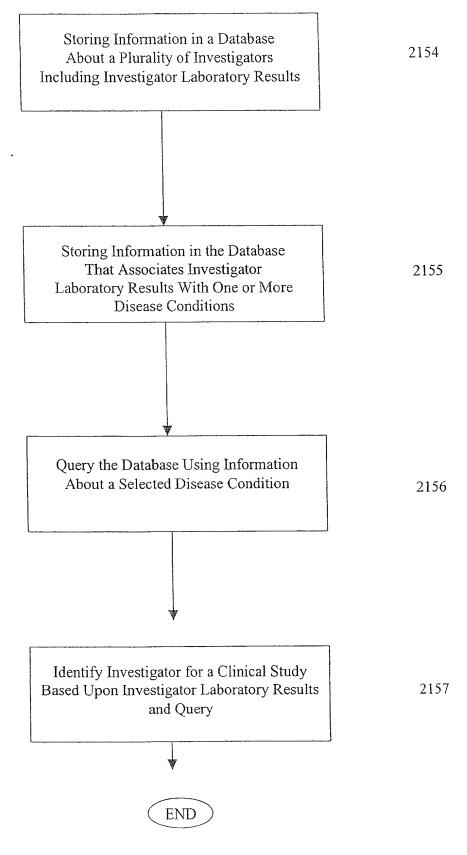


Fig. 210



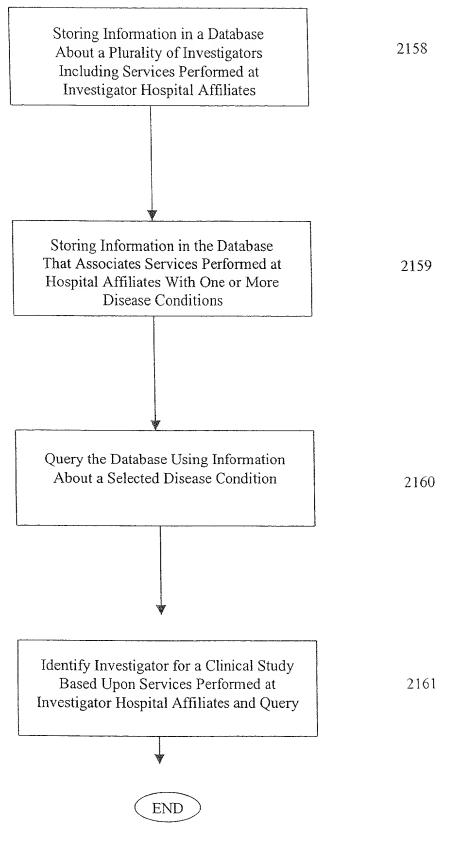
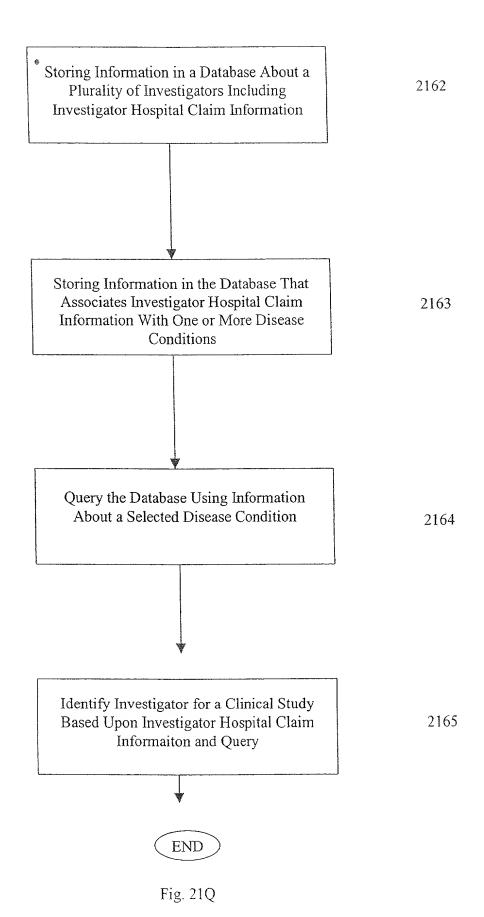
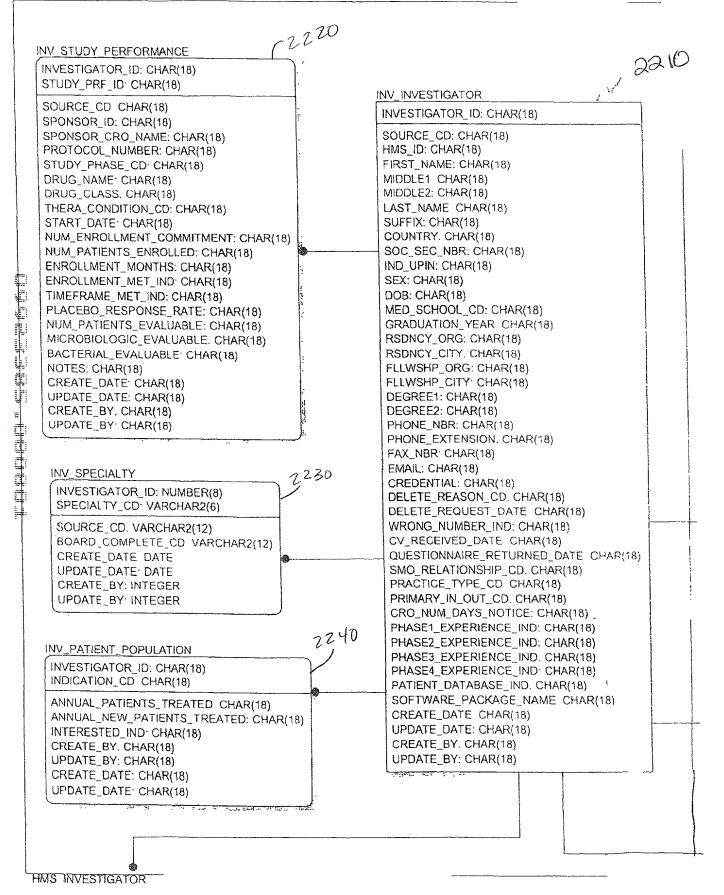
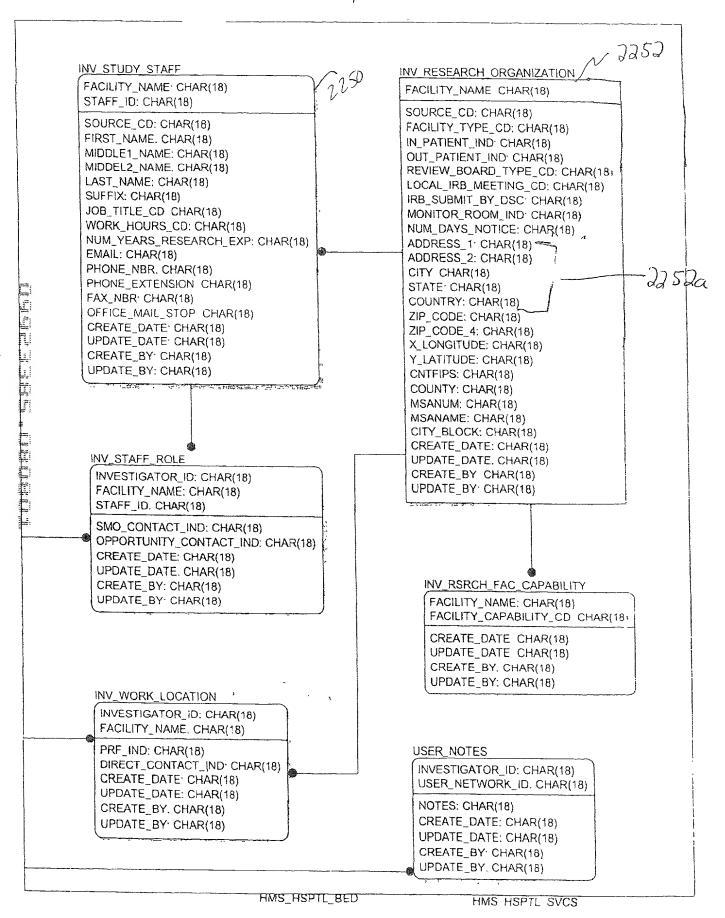


Fig. 21P





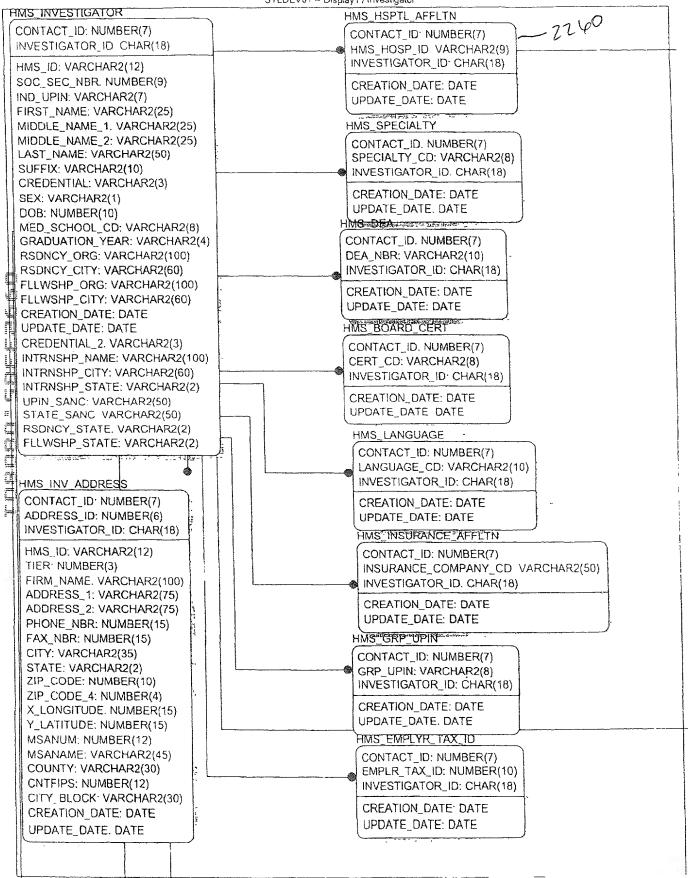
224



22B

73/69

STLDEV01 -- Display1 / Investigator



22C

74/89

STLDEV01 - Display1 / Investigator

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RESPIR\_SVCS: VARCHAR2(1)
SELFCARE\_SVCS: VARCHAR2(1)
SKNLT\_SVCS: VARCHAR2(1)
SOCSVC\_SVCS: VARCHAR2(1)
SPEECH\_SVCS: VARCHAR2(1)
THERD\_SVCS: VARCHAR2(1)
TRAUMA\_SVCS: VARCHAR2(1)
XRADT\_SVCS: VARCHAR2(1)
CREATION\_DATE: DATE
UPDATE\_DATE: DATE

22D

STLDEV01 - Display1 / Investigator

HMS\_HSPIL\_BED

CONTACT\_ID: NUMBER(7) HMS HOSP ID VARCHAR2(9) INVESTIGATOR\_ID: CHAR(18)

HMS STF BEDS: NUMBER(9) HMS HSP BEDS: NUMBER(9) HMS TOT BEDS: NUMBER(9) HMS STRM\_BEDS: NUMBER(9) HMS LTERM BEDS: NUMBER(9) HMS\_MDSRG\_BEDS: NUMBER(9) HMS\_ICU\_BEDS: NUMBER(9) BEDS\_OK VARCHAR2(5) ICU\_BEDS NUMBER(9) CCU\_BEDS: NUMBER(9) SICU\_BEDS. NUMBER(9) NICU\_BEDS: NUMBER(9) NINT\_BEDS. NUMBER(9) PICU\_BEDS: NUMBER(9) PEDI\_BEDS: NUMBER(9) OBGN BEDS. NUMBER(9) PSYC\_BEDS. NUMBER(9) BURN\_BEDS: NUMBER(9) ALCH BEDS: NUMBER(9) REHB, BEDS: NUMBER(9) OTHR BEDS: NUMBER(9) CREATION DATE: DATE

UPDATE\_DATE: DATE

HMS\_HSPTL\_SVCS

CONTACT\_ID: NUMBER(7) HMS\_HOSP\_ID: VARCHAR2(9) INVESTIGATOR ID CHAR(18)

AIDS SVCS VARCHAR2(1) ANSTH SVCS: VARCHAR2(1) ANGPLSTY SVCS. VARCHAR2(1) BLOODBNK SVCS. VARCHAR2(1) BMTRNSPL SVCS. VARCHAR2(1) BURNCTR\_SVCS: VARCHAR2(1) CRDCTH\_SVCS. VARCHAR2(1) CVSRGY SVCS. VARCHAR2(1) CHIRO\_SVCS\_VARCHAR2(1) CLPSY\_SVCS: VARCHAR2(1) CT\_SVCS: VARCHAR2(1) DENTL\_SVCS: VARCHAR2(1) ULTRSND\_SVCS. VARCHAR2(1) DIETRTY\_SVCS. VARCHAR2(1) ECARD\_SVCS\_VARCHAR2(1) ECONV SVCS. VARCHAR2(1); EMRGCY\_SVCS VARCHAR2(1) ESWL\_SVCS: VARCHAR2(1) LABAN\_SVCS: VARCHAR2(1) HEART\_SVCS, VARCHAR2(1) HRTLUNG\_SVCS: VARCHAR2(1) HEMDIAL\_SVCS: VARCHAR2(\*) HOMCRE\_SVCS VARCHAR2(1) HOSPCE\_SVCS: VARCHAR2(1) CCU\_SVCS: VARCHAR2(1) ICU\_SVCS: VARCHAR2(1) KIDNEY\_SVCS. VARCHAR2(1) LABCLNC\_SVCS: VARCHAR2(1) LIVER\_SVCS VARCHAR2(1) LUNG\_SVCS VARCHAR2(1) MEGVRAD\_SVCS. VARCHAR2(1) NEONUNT\_SVC\$ VARCHAR2(1) NICU\_SVCS. VARCHAR2(1) MRI\_SVCS: VARCHAR2(1) NEURO SVCS: VARCHAR2(1) NSURG\_SVCS: VARCHAR2(1) NUCMED SVCS: VARCHAR2(1) OBSRVA\_SVCS: VARCHAR2(1) **OBSTE SVCS VARCHAR2(1)** OCCTH\_SVCS: VARCHAR2(1) OPNHT\_SVCS: VARCHAR2(1) OPTOM\_SVCS: VARCHAR2(1) ORGBANK\_SVCS: VARCHAR2(1) ORGAN\_SVCS: VARCHAR2(1) OUTPAT\_SVCS, VARCHAR2(1) OUTSRG SVCS: VARCHAR2(1) PANCR\_SVCS: VARCHAR2(1) PEDIAT\_SVCS: VARCHAR2(1) PHARM\_SVCS: VARCHAR2(1) PHYTH\_SVCS VARCHAR2(1) PSTOP SVCS VARCHAR2(1) PSYED\_SVCS: VARCHAR2(1) PULMON\_SVCS: VARCHAR2(1)

RADIM\_SVCS VARCHAR2(1) RECTH\_SVCS: VARCHAR2(1)

HMS\_HSPTL

CONTACT\_ID. NUMBER(7) HMS\_HOSP\_ID. VARCHAR2(9) INVESTIGATOR ID. CHAR(18)

HSPTL\_NAME. VARCHAR2(100) DEPT\_NAME VARCHAR2(50) BRANCH\_NAME. VARCHAR2(50) ADDRESS\_1: VARCHAR2(75) ADDRESS\_2 VARCHAR2(75) CITY: VARCHAR2(25) STATE: VARCHAR2(2) ZIP\_CODE: VARCHAR2(6) ZIP\_CODE 4: VARCHAR2(4) PHONE NBR. VARCHAR2(13) CEO: VARCHAR2(50) FIPS5: VARCHAR2(10) COUNTY: VARCHAR2(50) MSANUM: VARCHAR2(12) MSANAME: VARCHAR2(50) CENSUS\_ID: VARCHAR2(20) X\_LONGITUDE: VARCHAR2(15)

Y\_LATITUDE: VARCHAR2(15) SRVC\_CD: VARCHAR2(5) CTRL\_CD: VARCHAR2(5) LOS\_CD: VARCHAR2(5) UNV\_HSPTL\_IND: VARCHAR2(1) TCH\_HSPTL\_IND. VARCHAR2(1) TEACHHOSP\_IND VARCHAR2(1) RESIDENCY\_IND: VARCHAR2(1) MED\_SCHL\_IND: VARCHAR2(1) ALLIED\_SCHL\_IND: VARCHAR2(1) JCAHO\_IND: VARCHAR2(1) MEDICARE\_IND. VARCHAR2(1) CANCERCTR\_IND: VARCHAR2(1) CLOSED\_IND: VARCHAR2(1)

CREATION\_DATE: DATE

UPDATE\_DATE DATE

HMS\_LICENSE

CONTACT\_ID: NUMBER(7) LICENSE\_STATE\_CD: VARCHAR2(2) INVESTIGATOR\_ID: CHAR(18)

LICENSE\_YEAR: NUMBER(4) CREATION\_DATE: DATE UPDATE\_DATE: DATE

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### FDA\_1572\_STAT

CONTACT\_ID: NUMBER(8)
INVESTIGATOR\_ID: CHAR(18)

NUM\_TRIALS\_LAST5: INTEGER
NUM\_TRIALS\_LAST4: INTEGER
NUM\_TRIALS\_LAST3. INTEGER
NUM\_TRIALS\_LAST2: INTEGER
NUM\_TRIALS\_LAST1: INTEGER
TOTAL\_TRIALS\_LIFETIME. INTEGER

FIRST\_YEAR: INTEGER LAST\_YEAR: INTEGER UPDATE\_DATE: DATE

4.37167 1 ... ... ...

#### FDA\_1572

CONTACT\_ID: NUMBER(7) FDA\_1572\_ID: NUMBER(7) INVESTIGATOR\_ID: CHAR(18)

HMS\_ID: VARCHAR2(12)
LAST\_NAME VARCHAR2(100)
FIRST\_NAME: VARCHAR2(25)
MIDDLE\_INITIAL VARCHAR2(1)
SUFX: VARCHAR2(5)
CRED1 VARCHAR2(8)
ORGNAME: VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)

RECEIPT\_DATE. DATE
RECEIPT\_YEAR: NUMBER(4)
ORG\_TYPE: VARCHAR2(3)
CREATION DATE: DATE

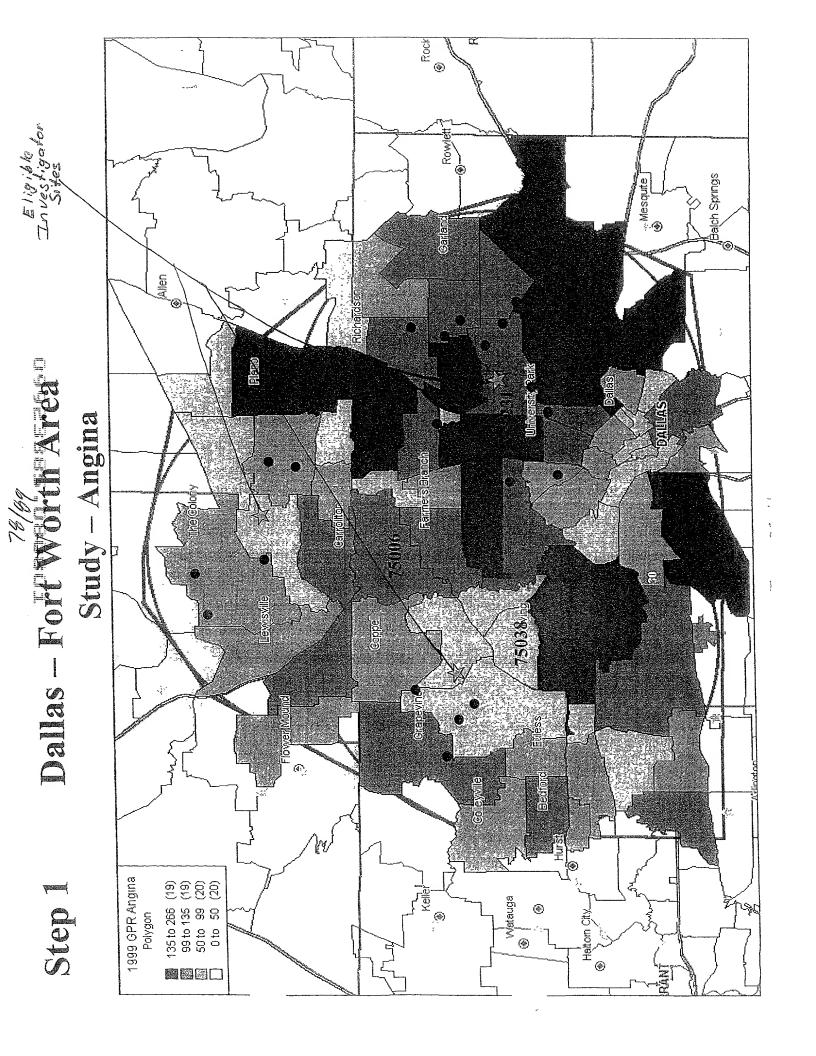
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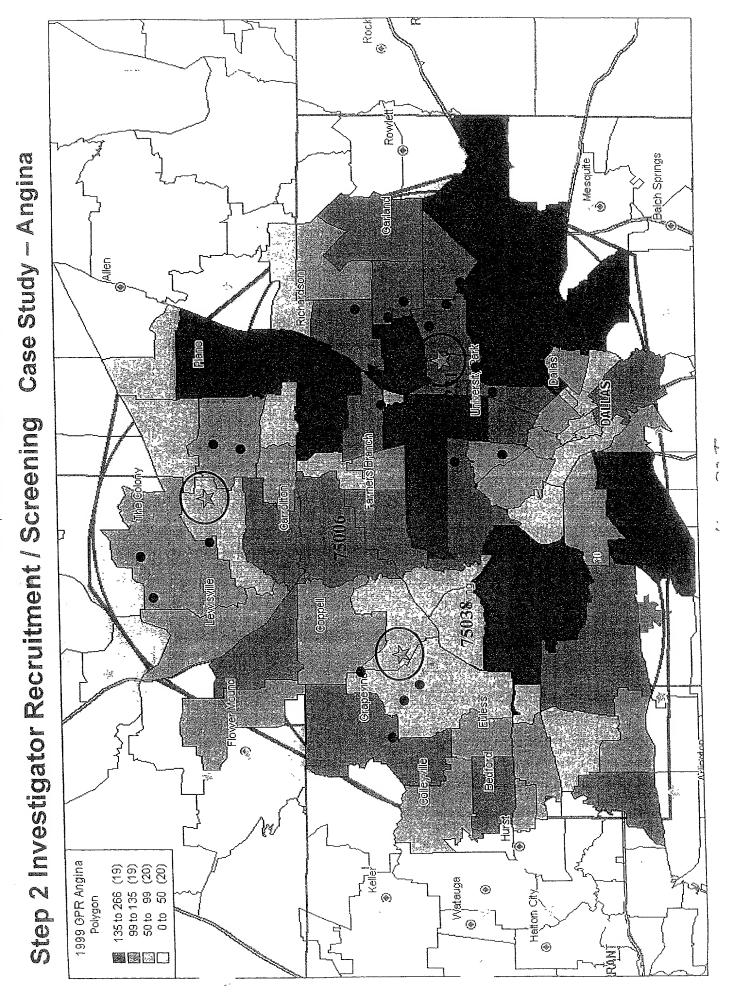
#### FDA\_483

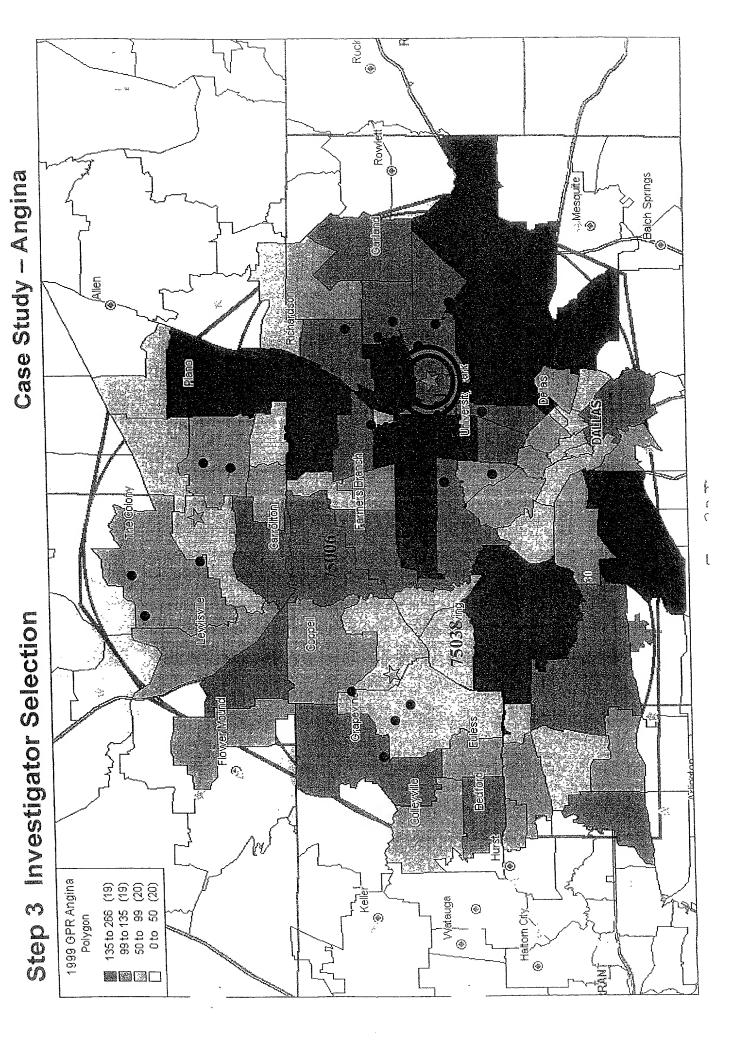
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FDA\_DFCNCY\_ID: NUMBER(8)
CONTACT\_ID: NUMBER(7)
INVESTIGATOR\_ID. CHAR(18)

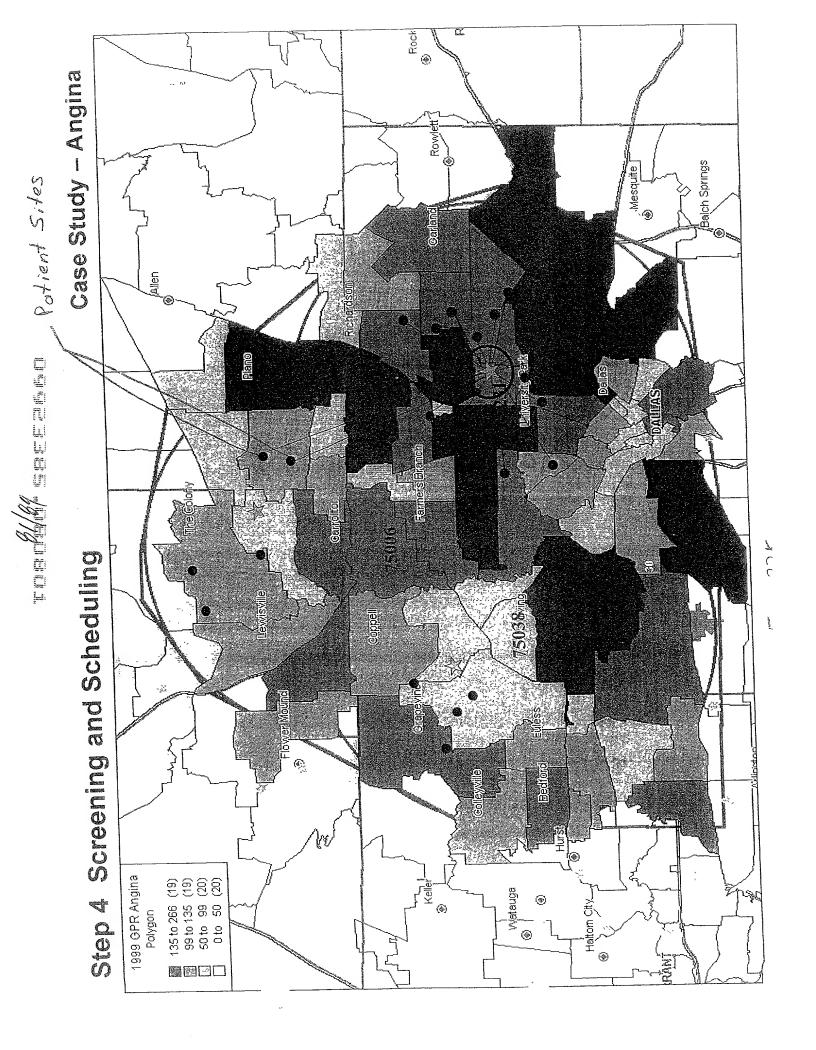
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FIRST\_NAME: VARCHAR2(25)
ORG. VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP\_CODE: VARCHAR2(14)
COUNTRY: VARCHAR2(60)
INSPCTN\_DATE: DATE
CLSSFCTN\_TYP: VARCHAR2(2)
CLSSFCTN\_CD VARCHAR2(5)
DFCNCY\_CD: NUMBER(2)
CREATION\_DATE. DATE

was for the count









Smith, John

Specialty Cardiovascular Disease Internal Medicine



Contact Information

Primary Research Facility

Study Stalf

Trial Experience

Provider

Hospital

Yellow = ABC Pharma Trial

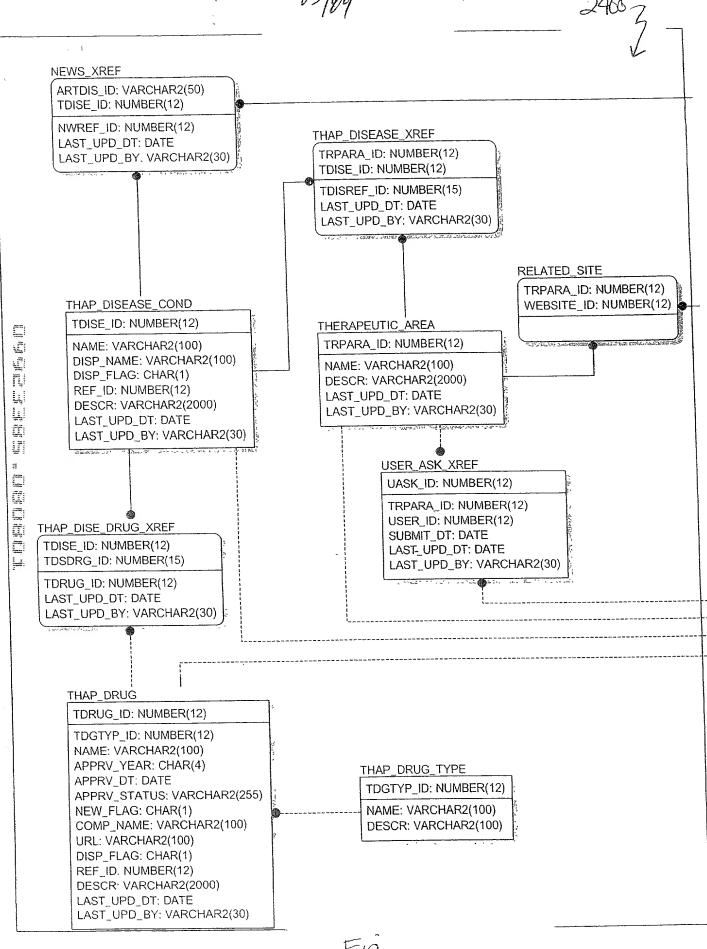
| Indication | Start Date | Enrollment<br>Commitment | Evaluable<br>Patients | Timeframe (months) | Enrollment<br>Percentage | ABC Pharma<br>Rank |
|------------|------------|--------------------------|-----------------------|--------------------|--------------------------|--------------------|
| APT        | 1/15/2001  | 12                       | 8                     | 12                 | 70%                      | 4                  |
| CHF        | 11/1/2000  | 10                       | 9                     | 9                  | 90%                      |                    |
| CHF        | 10/5/2000  | 10                       | 9                     | 9 /                | 90%                      |                    |
| CHD        | 7/1/2000   | 8                        | 3                     | 6                  | 40%                      | 2 .                |
| CAD        | 6/1/1999   | 15                       | 12                    | 6                  | 80%                      |                    |
| CHT        | 2/15/1999  | 8                        | 7                     | 10/                | 90%                      | 4 \                |
| CHF        | 3/1/1998   | 10                       | 8                     | /12                | 80%                      | 3.\                |
| CHD        | 3/22/1997  | 6                        | 4                     | 10                 | 60%                      |                    |
| CHD        | 6/1/1996   | 8                        | 6                     | 10                 | 80%                      |                    |

Aggregated data (2302)

Data supplied by sponsor viewing screen

(2304)

Fig 23



119. 24A

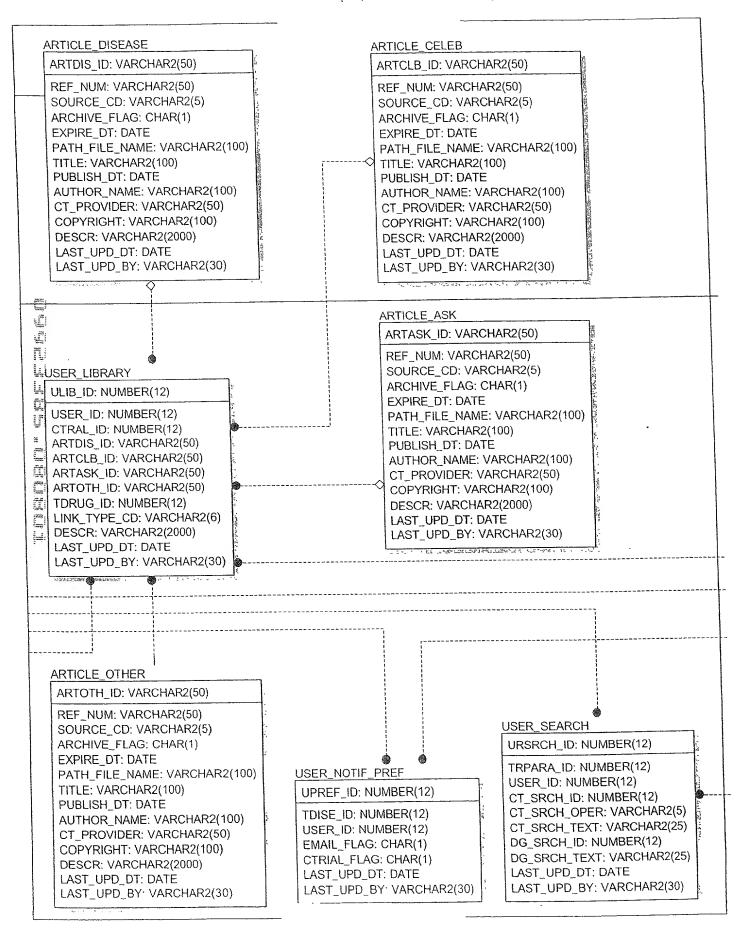
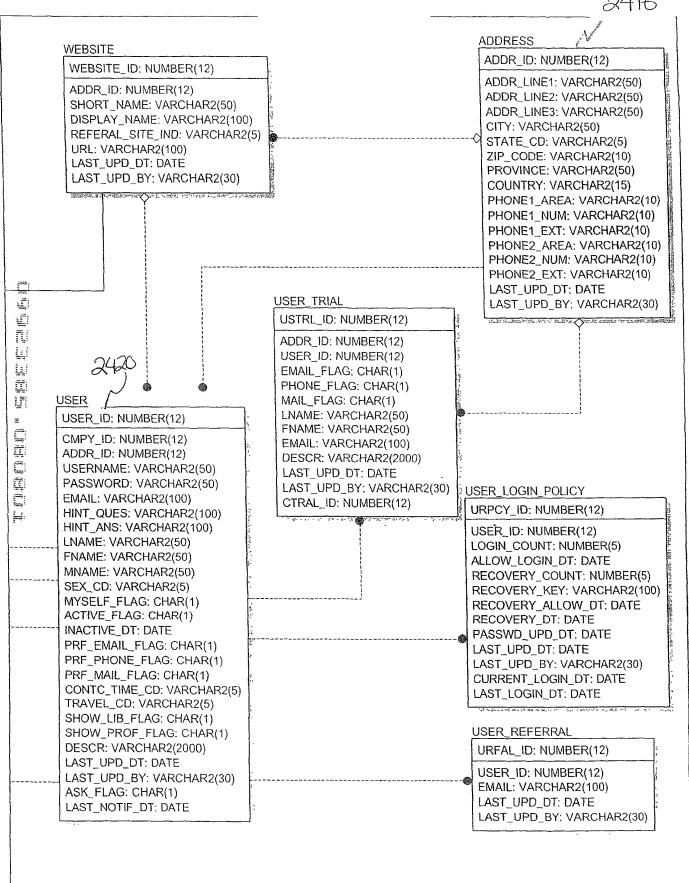


Fig. 243



## ACURIAN\_CONTENT\_TYPE

CONTYP\_ID: NUMBER(12) NAME: VARCHAR2(100) DESCR: VARCHAR2(100)

### ACURIAN\_NOTIFICATION

NOTIF\_ID: NUMBER(12)

Safe Saids Victor County and Last County County

NOTIF\_TYPE: VARCHAR2(100)
NOTIF\_DESC: VARCHAR2(100)
LAST\_NOTIF\_DT: DATE

# ACURIAN PUBLISH

PUBLISH\_ID: NUMBER(12) CONTYP\_ID: NUMBER(12) PUBLISH\_DATE: DATE TRPARA\_ID: NUMBER(12) ACULN\_COMPANY

COMPANY\_ID: NUMBER(8)

DESCRIPTION: VARCHAR2(132) COMPANY\_NAME: VARCHAR2(32)

TYPE\_CD: VARCHAR2(6)

K 2560

ACR MRGD TRIAL LISTING

SOURCE\_CD: VARCHAR2(6)

TRIAL\_LISTING\_ID: VARCHAR2(30)

SPONSOR\_COMPANY\_ID: NUMBER(8)

HEADER\_TXT: VARCHAR2(200)

DETAIL\_TXT: BLOB(4000)

DETAIL\_TXT\_URL: VARCHAR2(200)

SORT\_PRIORITY\_CD: VARCHAR2(6)

DISPLAY\_IND: VARCHAR2(1)

DISPLAY\_START\_DATE: DATE

DISPLAY\_END\_DATE: DATE

CREATE\_DATE: DATE

UPDATE\_DATE: DATE

ACR\_MRGD\_TRIAL\_INDICATION

SOURCE\_CD: VARCHAR2(6)

TRIAL\_LISTING\_ID: VARCHAR2(30)

THERAPEUTIC\_AREA\_CD: VARCHAR2(6)

INDICATION\_CD: VARCHAR2(6)

ACR\_MRGD\_TRIAL\_SITE

SOURCE\_CD: VARCHAR2(6)

TRIAL\_LISTING\_ID: VARCHAR2(30)

TRIAL\_SITE\_ID: NUMBER(8)

SITE\_TXT: VARCHAR2(800)

SITE\_TXT\_URL: VARCHAR2(200)

STREET1: VARCHAR2(100)

STREET2: VARCHAR2(100)

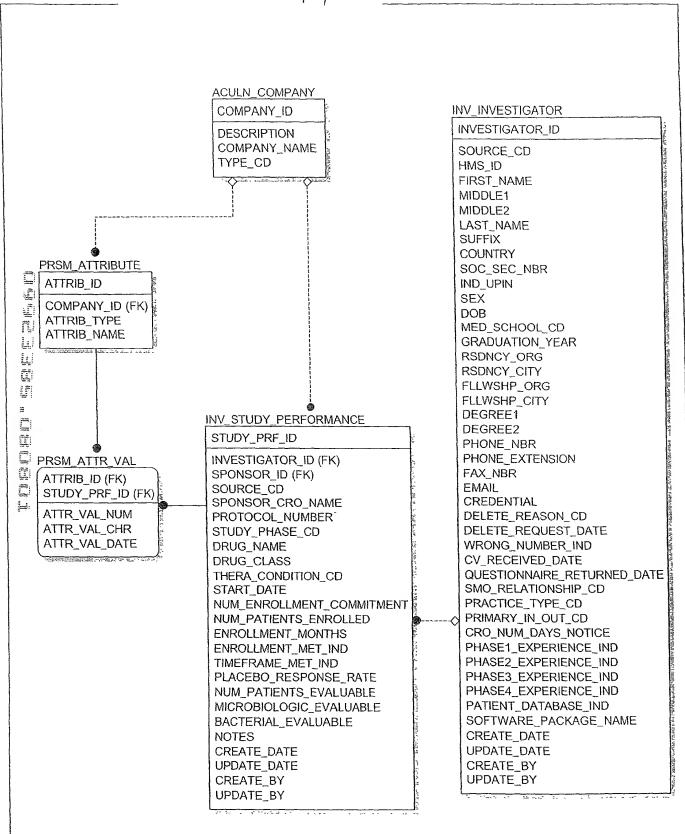
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STATE: VARCHAR2(2)

ZIP: NUMBER(5)

ZIP4: NUMBER(4)

Fig. 25





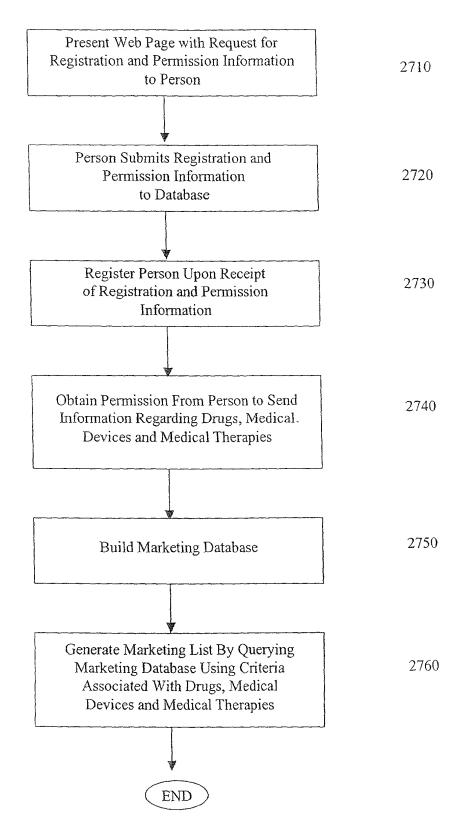


FIG. 27